510 (K) Summary
JOVUS Eagle Eye™ F/X 2.9F Intravascular Ultrasound Imaging Catheter

Dave Prepared: April 15, 2003

JUN 2 3 2003

Submitted by: JOMED Inc.
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Contact person: Lorry W. Huffman
Regulatory Affairs Manager

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Device Name: JOVUS Eagle Eye™ Intravascular Ultrasound Imaging Catheter (Eagle Eye™ IVUS Catheter)

Classification name:	**Class**
• 870.1200 Diagnostic Intravascular catheter	II
• 892.1560 Ultrasonic pulsed echo imaging system	II

Predicate Device:
The JOMED Inc. JOVUS Eagle Eye™ F/X 2.9F Intravascular Ultrasound (IVUS) Imaging Diagnostic Catheter is substantially equivalent to the Avanar™ F/X 2.9F Intravascular Ultrasound Imaging Catheter cleared under K000820 on June 5, 2000.

Device Description:
The JOVUS Eagle Eye™ F/X catheters contain a catheter-tip ultrasound device that applies ultrasound energy directly into the interior vessel wall of the patient to obtain an image of the vessel. This device is not currently indicated for use in cerebral vessels. The JOVUS Eagle Eye F/X catheter accommodates a 0.014" guide wire.

The JOVUS Eagle Eye™ F/X catheter utilizes an integral guide wire lumen in which the catheter tracks over the guide wire at the distal tip. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the catheter tip.

The JOVUS Eagle Eye™ F/X catheter is introduced percutaneously or via surgical cutdown into the vascular system. A linear array ultrasonic transducer situated circumferentially near the tip of the catheter produces real time cross-sectional images of coronary and peripheral vessels.

The JOVUS Eagle Eye™ F/X 2.9F catheters may only be used with the In-Vision™ Imaging System. This catheter will not operate if connected to any other imaging system.

Intended Use:

JOVUS Eagle Eye™ F/X catheters are designed for use in the evaluation of vascular morphology, such as lesion geometry in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels.

JOVUS Eagle Eye™ F/X ultrasound imaging catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures, during device (e.g. stent) placement, and/or other percutaneous vascular procedures.

Device Technological Characteristics and Comparison to Predicate Device:

The modified device, JOVUS Eagle Eye™ F/X catheter, was developed utilizing a higher performance material in the electrical contact area and improved manufacturing processes to achieve improved catheter performance. The JOVUS Eagle Eye™ 2.9F Intravascular Ultrasound Imaging Catheter utilizes the same fundamental scientific technologies and has the same intended use as that of the predicate device, Avanar™ F/X 2.9F Intravascular Ultrasound Imaging Catheter.

The scanner, hub, and connector assembly have been slightly modified as listed below:

- The backing material changed.

- The bump shaft has been changed from black to teal in order to match new corporate identity colors
- The microcable bundle configuration has been modified for improved electrical performance.
- Tolerances have been added to the catheter dimensions to provide a more realistic inspection parameter.

Performance Data:

Applicable testing is being performed in accordance with the Master Design Verification Plan including a Risk Analysis addressing the impact of modifications to the device and components. The test results will be found to be comparable to those of the predicate device, Avanar™ F/X 2.9F Intravascular Ultrasound Imaging Catheter. The new backing material was tested for biocompatibility according to ISO 10993-1 and the results met the predetermined acceptance criteria.

Conclusion:

JOVUS Eagle Eye™ F/X 2.9F Intravascular Ultrasound Imaging Catheter has the same *Intended Use* and utilizes the same *fundamental scientific technology* as that of the predicate device, Avanar™ F/X 2.9F Intravascular Ultrasound Imaging Catheter cleared under K000820 on June 5, 2000. The performance data and a declaration of conformity with design controls support a determination of substantial equivalence of the modified device, JOVUS Eagle Eye™ Intravascular Ultrasound Imaging Catheter, to the predicate device, Avanar™ F/X 2.9F Intravascular Ultrasound Imaging Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2003

Jomed Inc.
c/o Ms. Lorry W. Huffman
Regulatory Affairs Manager
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Re: K031346
Trade Name: JOVUS Eagle Eye™ Intravascular Ultrasound Imaging Catheter (Eagle Eye™ IVUS Catheter)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II (two)
Product Code: DQO
Dated: June 10, 2003
Received: June 12, 2003

Dear Ms. Huffman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031346

Device Name: JOVUS Eagle Eye™ F/X Intravascular Ultrasound Imaging Catheter

Indications for Use:

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JOVUS Eagle Eye™ F/X ultrasound imaging catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.19)

OR

Over-the-Counter Use _____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031346